

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Docket No. 400140)

In re the Application of:

DONALD K. JONES et al.

Serial No.: 09/880,506

Filed: June 13, 2001

For: OCCLUDING VASCULATURE OF A
PATIENT USING EMBOLIC COIL WITH
IMPROVED PLATELET ADHESION

To: Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Art Unit: 3743

Examiner Kathryn Odland

RECEIVED

MAY 26 2004

TECHNOLOGY CENTER R3700

DECLARATION UNDER 37 C.F.R. SECTION 1.131

I, Vladimir Mitelberg, declares as follows:

1. I am a co-inventor of the invention disclosed and claimed in the above identified application.

2. I have worked in the field of biomedical engineering, including embolization devices, for over eight years and in mechanical engineering for over twenty years.

3. It is my understand that U.S. Patent No. 6,280,457 to Wallace et al., filed June 4, 1999, has been cited by the Patent and Trademark Office in support of rejections of claims 1-4, 6-14, 16, 17, 20, and 27 of the above-identified application.

4. The invention of this application was made prior to June 4, 1999, the date of filing of U.S. Patent No. 6, 280,457. More specifically, the invention was made and completed, and actually reduced to practice, all in the United States of America, prior to June 4, 1999, as evidenced by the attached exhibits.

5. Exhibit A is a date-redacted copy of an invention record disclosure signed by Donald Jones and me. Exhibit A reports on work performed by us and/or under our direction and control in the United States of America prior to June 4, 1999, in connection with making embolic coils for occluding the vasculature of a patient, which devices were made and reduced to practice before June 4, 1999.

6. With respect to Exhibit A (the invention record) referred to in paragraph 5 above, the photographs set forth in the last page of this invention record were taken by Donald Jones of the roughened coils prior to submitting them for evaluation. The page having the number 028122 shows service requests. The picture on the bottom is a service request in which the coils were submitted for evaluation. Four photomicrographs were taken as indicated by the middle box and these four microphotographs were the results of the service requests. These photomicrographs are on the page of Exhibit A following the service requests. All of these photographs and service requests were taken and made prior to June 4, 1999.

7. Exhibit B are date-redacted copies of experiments performed on baboons, in connection with occluding the vasculature of the baboons, which experiments were performed before June 4, 1999.

8. The work referred in paragraph 7 above, included ex-vivo tests outside of the body using the baboon. A silicone tube was connected to the artery of the baboon. Blood flow was through the silicone tube and back to the baboon. In the silicone tube, aneurysms were formed on the tube itself. A delivery catheter was used to place roughened embolic coils inside of the aneurysms, with the help of a pusher mechanism. Live blood was run through the system and radioactive platelets accumulated on the

coils. The coils used were textured 5 mm. complex coils. By using a gamma camera imager, the radioactivity was measured. Non-textured coils were also used. It was found that there were greater amount of platelets on the roughened coils then on the non-roughened coils. From these experiments we were able to conclude that the introduction of the textured coils in the aneurysm would enhance platelet adhesion.

9. In view of my experience in biomedical engineering (including embolization devices) prior to June 4, 1999, I was confident that the vasculature of a patient could be successfully occluded by providing a plurality of embolic coils having a proximal portion that is held by the detachment portion and a distal portion, with the proximal portion that is held by the detachment portion being relatively smooth and the distal portion having a relatively textured surface. I found that the textured surface provides improved platelet adhesion compared to a non-textured surface, to promote clotting. As a result of the experiments, I was confident that the embolization device having a roughened surface was suitable for placement in a catheter for being conventionally implanted with an introducer having a detachment portion to provide improved platelet adhesion compared to a non-textured surface, to promote clotting. Accordingly, in my view, the invention was reduced to practice on a date prior to June 4, 1999, because I was confident that clinical versions of the prototype could be sterilized and clinically used with success to embolize aneurysms in patients.

10. I hereby declare that all statements made herein and of my own knowledge are true, and that all statements made on information and belief are believed to be true; and I further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or

imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or patent issued therefrom.

Date: May 11-2004

V. Mj-
Vladimir Mittelberg

PATENT

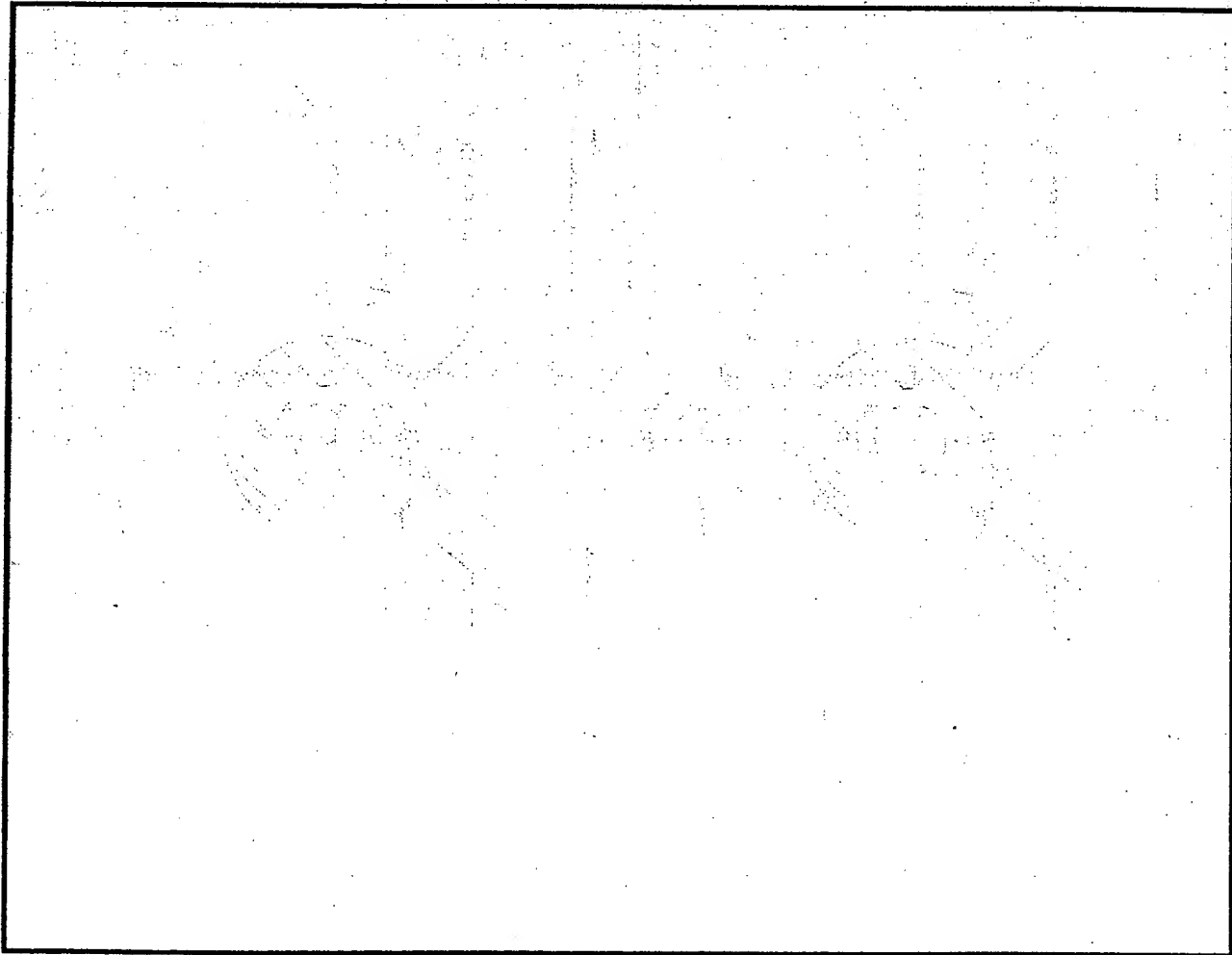
DEPARTMENT

Cordis

00/140

DESCRIPTIVE TITLE: Coil Surface Modification

- I. **INSTRUCTIONS:** This form should be typed, except for the signatures and dates. Disclose only one invention on this Invention Disclosure form, and complete the entire form as fully as possible. Forward the completed form to the Legal Department, signed and dated by all inventors and two witnesses. Refer to this Invention Disclosure by the number assigned to it when receipt is acknowledged. Attach additional sheets if more space is required. Each original piece of paper must be signed and dated by every inventor and by each witness.
- II. **ILLUSTRATION:** *Include a drawing, sketch, photograph, flow chart, or preferably an engineering quality printout of the invention.*



Name & Signature of Inventor(s):

Date

Witnesses

Date

V. H. H. G.
Donald E. H. G.

E. H. G.
H. H. G.

EXHIBIT A

III. EXPLANATION OF INVENTION: *Describe the invention completely, including all essential elements.*

The invention is a surface modified embolization coil. The surface has been texture by abrasion or "sand blasting". Fifty-micron diameter alumina particles were used to texture the surface of the platinum tungsten wire used to form the coils. It is believed that the textured surface provides improved platelet adhesion thus promoting clotting and subsequent endothelialization. SEM micrographs and optical pictures of the textured vs. non-textured are attached. Testing using radiolabeled platelets was conducted to evaluate an ex vivo aneurysm model. In the model, aneurysms treated with textured coils were compared to aneurysms treated with non-textured coils. The textured coils showed an increase in the platelet deposition of about 50% over the non-textured coils.

IV. NOVEL FEATURES AND ADVANTAGES: *What is new that was not previously known, and why is this important.*

Other surface modification techniques such as coating or ion implantation require expensive and elaborate equipment to modify the coils which add an additional component. This method does not impart any new materials to the coil that would require new biocompatibility testing and can be done inexpensively.

V. MODIFICATIONS: *Describe all possible modifications or alternate embodiments.***VI. RELATED DOCUMENTS:** *List all known relevant art references (patents, publications, commercially available products, etc.) Please supply copies of the documents, if available.*

Patents:

Publications:

Signature of Inventor(s):

Date:

Witnesses:

Date:

V. Huf

Donald E. Green

E. Huf
Donald E. Green

VII. INVENTORS:

DEPARTMENT

Donald K. Jones

First Inventor's Full name (Please type:)

Signature: Donald K. Jones

Date:

Vladimir Mittelberg

Second Inventor's Full Name (Please type:)

Signature: V. Mittelberg

Date:

VIII. WITNESSES: This invention was disclosed to and understood by:

Full Name of First Witness (Please type: Eric Cheng)

Signature: Eric Cheng

Date:

Full Name of Second Witness (Please type:)

Boris Shkolnik

Signature: Boris Shkolnik

Date:

IX. ADDITIONAL INFORMATION:

Invention is recorded on page(s): of Notebook No.: dated:

Earliest date: and place: CES where inventors first
thought of the present invention.

First written description (date and present location):

First sketch of the invention (date and present location):

Earliest date: and place: where first operating
model
was completed.

Present location of model:

Earliest date of use of the invention (actual or contemplated):

Earliest shipping date (actual or contemplated):

Service Request

Job number, assigned by
supplying organization 32027

Requestor	To <u>CPOA, EPL LAB</u>	Project/Charge _____
	From (organization) <u>CE</u>	Date required _____
	Location _____	
	For information contact <u>PETER GUINONES</u>	<u>x 8620</u>
	Description of request <u>8667A</u>	
	<u>PLEASE PROVIDE SEM PHOTOS</u> <u>OF SURFACE OF COILS PROVIDED</u> <u>FOR ROUGHNESS EVALUATION.</u>	
Requested by <u>P. Guinones</u>	Date _____	
Approved by _____	Date _____	

Supplier	Date received _____
	Labor cost _____
	Material cost _____
	Purchased Materials, services or equipment required <u>notebook 92071-46</u>
	Completion date _____
	Comments <u>Electron optical micrographs were taken</u> <u>of each sample at low & high</u> <u>magnifications to show surface</u> <u>roughness conditions.</u>
Estimate by <u>John Daub</u>	Date <u>1/1/80</u>

Approvals	Cost and completion date accepted by requestor _____
	Signature _____ Date _____
	Comment _____

	Supplier acceptance by <u>BR</u> Date <u>1/1/80</u>

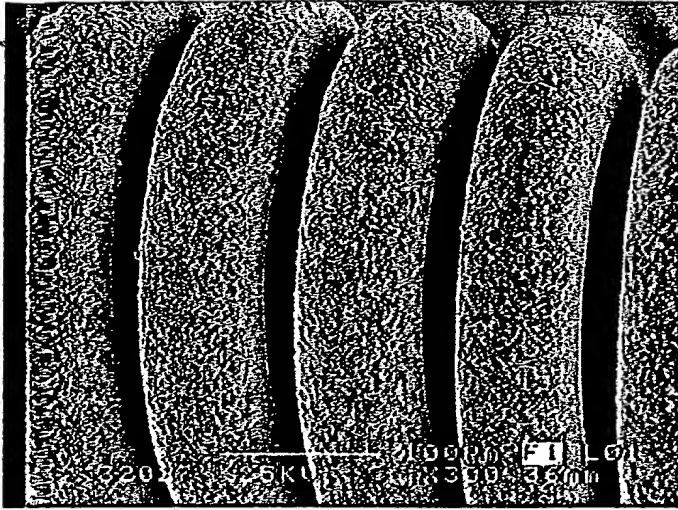


Figure 1-(233x) Sample with rough surface

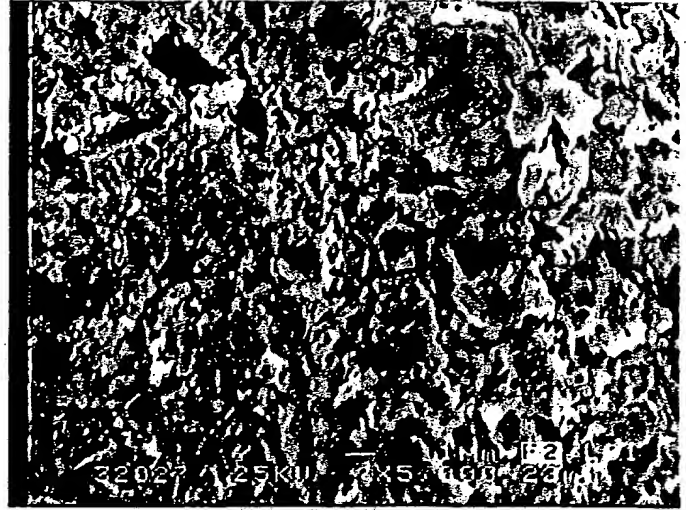


Figure 2-(3880x) Sample with rough surface

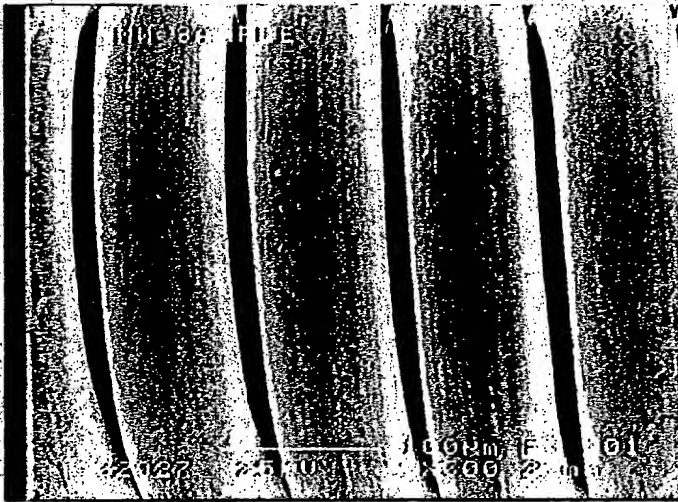


Figure 3-(233x) Sample "MW" with smooth surface.

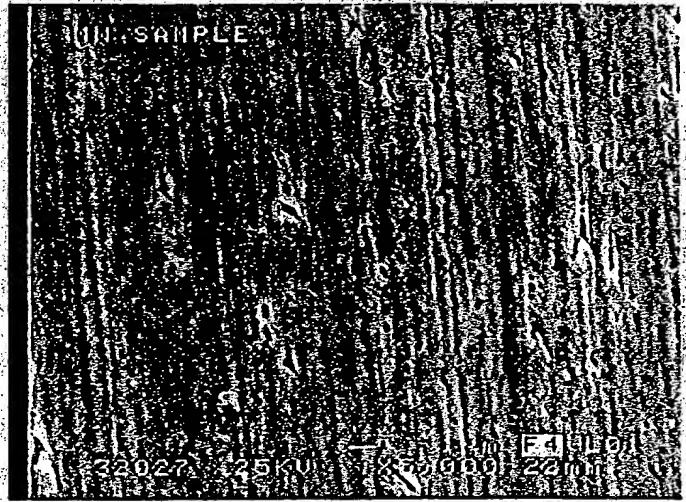


Figure 4-(3880x) Sample "MW" with smooth surface.

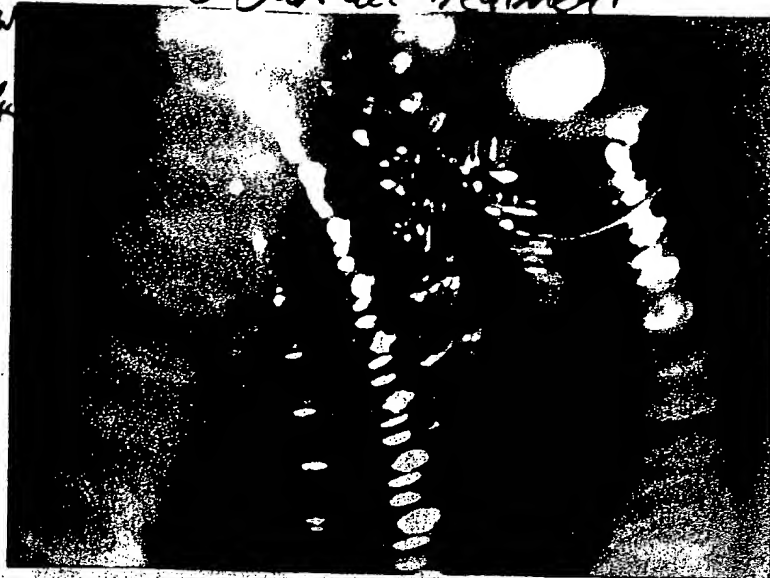
Double force

40 X Mag

.003" thick

5mm
Complex
(20-mil)

No Surface Treatment



PAT

DEPAR

DXF

40 X Mag

.003" thick

5mm
Complex
(20-mil)

Surface Treatment



2 Rough
- Fine

Surface Abraded using AcanBRAD - 5 2mm
50 micron blend of Al₂O₃ (Part No. AP105)

DXF

**Computer
Data Partition**

Study Description

Aneurysm: Run #1 untextured 5mm dlm. complex colls. Tail: from Aneu. #1 stopped 1.25" from aneu. #2. Tail from Aneu #2 extended 16"

flow stopped at 1hr 25min - shunt was flushed

Remarks

TIm	ROI		43x48	ROI	CPM		
	Min	CPM			CPM/bkg	Thrombus	Standard
5	145	103	42.00	0.000689	0.03		
10	162	165	-3.00	0.000689	0.00		
15	229	194	35.00	0.000689	0.02		
20	240	237	3.00	0.000689	0.00		
25	323	242	81.00	0.000689	0.06		
30	331	307	24.00	0.000689	0.02		
35	398	344	54.00	0.000689	0.04		
40	444	401	43.00	0.000689	0.03		
45	506	396	110.00	0.000689	0.08		
50	538	406	132.00	0.000689	0.09		
55	575	461	114.00	0.000689	0.08		
60	633	478	155.00	0.000689	0.11		
65	668	486	182.00	0.000689	0.13		
70	860	512	148.00	0.000689	0.10		
75	800	563	237.00	0.000689	0.16		
80	814	528	286.00	0.000689	0.20		
85	883	644	239.00	0.000689	0.16		
90	938	816	322.00	0.000689	0.22		
95	924	650	274.00	0.000689	0.19		
100	958	688	270.00	0.000689	0.19		
105	922	694	228.00	0.000689	0.16		
110	984	674	280.00	0.000689	0.20		
115	986	684	322.00	0.000689	0.22		
120	959	652	307.00	0.000689	0.21		
125	897	666	231.00	0.000689	0.16		
130	872	660	212.00	0.000689	0.15		
135	996	700	266.00	0.000689	0.20		
140	1010	686	324.00	0.000689	0.22		
145	1030	754	276.00	0.000689	0.19		
150	986	704	282.00	0.000689	0.19		

A3	172
A341	247
GE	low
8 x 10	med
15%	word
	byte

Plt Cnt Pre	295
Plt Cnt Pst	204
WBC	11.5
Hct Pre	45.40%
Hct Post	42.10%
Flow (ml/min)	100/clamp

Whole Blood	121465
Plasma	16014
Fraction	92.8%
Free	7.2%
Volume (cc)	3

Blood Std CPM	1672
Bkg CPM	291
Bkgd CPM 1	1361
CPM In-plts	1281.589
CPM/ml In-plts	427.1963
FINAL	0.000691

ROI

[illegible]

Collimator	>	low
Matrix		med
128	>	word
		byte

Whole Blood	121465
Plasma	16014
Fraction	92.8%
Free	7.2%
Volume (cc)	3

ROI ROI[illegible]